



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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WARNING LETTER

February 11, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert W. Strack, Owner/Treasurer
Oro Blanco, Inc.
P.O. Box 567
Hudson, Colorado 80642

Ref#: DEN-05-07

Dear Mr. Strack:

On September 24-29, 2004, the Food and Drug Administration (FDA) inspected your cheese processing plant, located at 19467 County Road 18, Ft. Lupton, Colorado. This inspection was in follow-up to testing of Oro Blanco Manchiva Enchilado Goat Cheese, lot #021205, which confirmed the presence of high amounts of *Escherichia coli* (*E. coli*) and Enterotoxigenic *E. coli* (ETEC). Our September 24-29, 2004 inspection has revealed multiple violations of FDA's Current Good Manufacturing Practice (CGMP) regulation found in Title 21, Code of Federal Regulations, Part 110 (21 C.F.R. Part 110). These violations make your products adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 342(a)(4)), in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The specific violations are identified and explained below. You can find the Act and FDA's regulations through links in FDA's home page, located at <http://www.fda.gov>.

The following conditions in your facility violate CGMPs and adulterate your food products under section 402(a)(4) of the Act:

- You failed to use adequate pasteurization to destroy or prevent the growth of undesirable microorganisms in food [21 CFR 110.80(b)(4)]. Our review of 39 temperature recorder chart records found seven occasions where minimum time/temperatures of [redacted] minutes/[redacted] F were not met. For example, on August 28, 2004, the pasteurizer temperature never reached [redacted] F.

Failure to manufacture and store foods under conditions and controls necessary to minimize contamination [21 CFR 110.80(b)(2)]. For example, a transfer hose

used to fill the cheese vats was allowed to touch the pasteurized milk in the vat during filling. Our investigator routinely observed other transfer hoses in contact with the floor. Additionally, a cheese rake with visible water droplets was stored directly over pasteurized milk in the cheese vat.

Failure to provide adequate screening or other protection against pests [21 C.F.R. § 110.20(b)(7)]. For example, there was a one-inch gap at the bottom to the door between the production room and milking parlor; the bathroom window was open and unscreened; and air vents were not screened. Live flying insects were observed in the production area.


We note that the violations cited above are of special concern given the fact that one of your products was previously found to be contaminated with *E. coli* and ETEC, and that our inspection revealed the presence of *E. coli* in the production environment.

These violations are not meant to be an all-inclusive list of deficiencies in your facility. It is your responsibility to ensure that all of your food products are manufactured in accordance with applicable statutes and regulations. We advise you to take prompt action to correct any violations, including those identified in this letter. Failure to promptly correct violations may result in regulatory action without further notice, such as an action to seize your products or enjoin your firm's operations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct the noted violations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deficiencies.

Your reply should be sent to Shelly L. Maifarth, Compliance Officer, at the address provided in the letterhead. If you have any questions concerning this letter, you may contact Ms. Maifarth at (303) 236-3046.

Sincerely,



B. Belinda Collins
District Director